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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Dirk Johannes Schaefer

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/009,527	Applicant(s) SCHAEFER ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39 and 41-68 is/are pending in the application.
- 4a) Of the above claim(s) 45-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-39, 41-44, 67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/08 has been entered.

Response to Amendments

Applicant's amendments filed 3/12/08 to claim 36 have been entered. No claims have been cancelled or added in this reply. Claims 36-39 and 41-68 remain pending in the current application, of which claims 36-39, 41-44, 67, and 68 are being considered on their merits. Claims 45-66 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

Claim Objections

Claim 36 is objected to because of the following informalities: the word "interlockingly" is misspelled in element (g). Appropriate correction is required.

Claim Rejections - 35 USC § 112

Any rejections of record under 35 U.S.C. § 112 not specifically addressed below are withdrawn in light of the claim amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-39, 41-44, 67, and 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 36 has been amended to recite a composition comprising, inter alia, “cartilaginous matrix” and “bone matrix,” terms that are not recited in the specification and that have no universally accepted definition in the art. Applicants appear to be shifting the scope of the invention, and the basis for this shift is not clear.

This rejection would be overcome if applicants pointed out by page and line number the basis for these new limitations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-39, 41-44, 67, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is drawn to a composition that comprises a “joint side consisting essentially of cultured chondrocytes and/or chondroblasts and cartilaginous matrix” and an “anchor side consisting essentially of cultured osteoblasts and/or osteocytes and bone matrix” that is produced by an 8-step method. However, none of these steps

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include “chondroblasts,” “cartilaginous matrix,” “osteoblasts,” or “bone matrix.” It is not clear how these necessary (the matrices) and optional (the blast cells) relate to the overall structure of the composition. The steps in the product-by-process limitations do not appear to make the product as recited in the preamble. Clarification is required. This is a new ground of rejection necessitated by the amendments, so applicants’ comments do not specifically address this issue. However, regarding the withdrawn rejections, applicants note that the specification contains a description of the product (Reply, page 9, paragraph 4). However, while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is cautioned against relying on limitations recited only in the specification, not in the claims, in future arguments.

Because claims 37-39, 41-44, 67, and 68 depend from indefinite claim 36 and do not clarify this point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Furthermore, claim 68 requires that the connection in claim 36 be “by fibrin adhesion,” which is confusing. Claim 36 does not require that the composition comprise fibrin, and claim 68 does not distinctly claim the manner in which the fibrin is physically and structurally related to the rest of the composition. It is not clear whether claim 68 requires the composition of claim 36 to further comprise fibrin. Applicant alleges that the specification contains basis for this limitation (Reply, page 9, paragraph 4), but while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Clarification in the **claims** is still required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36, 38, 41, 42, 44, 67, and 68 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay (1991, U.S. Patent 5,053,050) taken in view of Mikos (1996, U.S. Patent 5,522,895), Rosenthal et al. (1995, U.S. Patent 5,466,462), and Jakob et al. (WO 99/21497; and German-to-English translation). Regarding Jakob et al., the page and paragraph numbers in this rejection refer to the English translation, which was made of record 10/24/05.

Itay teaches a composition produced *in vitro* that comprises a biocompatible carrier material (e.g. a fibrin matrix) and chondrocytes that have been expanded and enriched in culture medium; the composition may be implanted into defective bones

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(Examples 1-3 and The Process). The composition of Itay can be produced in any shape, including cylindrical shapes (column 4, line 68) and the particular shape of the damaged area (column 5, lines 3-4), and in any size (Example 3). Because the composition of Itay comprises a fibrin matrix, Itay teaches fibrin adhesion.

Itay does not teach an *in vitro* composition comprising both cultured cartilage cells and cultured bone cells, said composition comprising cartilage cells on one face thereof and bone cells on the opposing face.

Mikos teaches seeding osteoblasts in growth medium onto a biodegradable polymer (column 4, lines 23-29), allowing the suspension to wick into the polymer foam (lines 29-33), and culturing the cells on the polymer to allow them to attach to the foam (lines 35-55). Mikos teaches that the culturing step allows the osteoblasts to secrete their own extracellular matrix, facilitating cell attachment and gradually eliminating the need for the polymer foam (column 4, lines 46-51). Mikos teaches that biodegradable polymers that form fibers are known in the art and include polyglycolic acid (column 3, lines 30-47). The composition of Mikos may take any desired anatomical shape according to the mold used to shape the polymer (column 3, lines 48-62).

Rosenthal et al. teach that fibrin and polyglycolic acid are functional equivalents in the tissue engineering and wound healing arts (column 1, lines 15-23).

Jakob et al. teach a composition comprising both a bone side and a cartilage side; the composition of Jakob et al. is a column of tissue that has been removed from a donor site at the articular face of a bone (page 2, paragraph 3; Figures 1, 5-7, 9, and 10). Jakob et al. also teach a composition comprising cartilage cells cultured *in vitro* on

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bone-replacement material (page 5, paragraph 3; page 16, paragraph 3; Figures 11 and 12). The composition of Jakob et al. may have a circular cross-section (page 11, paragraph 4; page 12, paragraph 4; and Figures 13-16) or may have any shape (page 15, paragraph 3).

Claim 36 is a product-by-process claim; claims 37-39, 41-44, 67, and 68 depend from said claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since

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in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established.

We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, claim 36 requires culturing osteoblasts and chondrocytes separately, then populating one piece of carrier material with the former and a second piece of carrier material with the latter and connecting the two pieces of material together. There is no evidence on the record to indicate that the product made by such steps would be materially different from one made by, e.g., seeding chondrocytes on one end of a single piece of carrier material and osteoblasts on the other end, or by isolating a portion of the articular face of a bone as taught by Jakob. Such evidence is required to overcome this rejection.

It is noted that claim 36 recites "consisting essentially of." M.P.E.P. § 2111.03 clearly indicates that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the

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basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). For the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, **absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.”** If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” **applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention.** *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, “consisting essentially of” in claim 36 has been interpreted as “comprising” for the purpose of art rejections. Furthermore, as discussed in a previous Office action, the claim limitations “cartilaginous matrix” and “bone matrix” are not provided with limiting definitions in the specification; indeed, they do not appear to be recited in the specification at all. It is not clear what components may and may not be included in the claimed composition without materially affecting its basic and novel characteristics.

A person of ordinary skill in the art would have had a reasonable expectation of success in combining the *in vitro* cartilage construct of Itay and the *in vitro* bone construct of Mikos because Rosenthal et al. teach that the biodegradable polymers on which each construct is based are functional equivalents for each other; therefore, the

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cartilage construct of Itay could be modified to include bone cells on one side, and the bone construct of Mikos could be modified to include cartilage cells on one side. The skilled artisan would have been motivated to combine the teachings of Itay and Mikos because Jakob et al. teach that compositions that have bone tissue on one side and cartilage tissue on the opposite side provide efficient repair of defects on the articular face of bone joints (page 15, paragraph 2, *inter alia*).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the *in vitro* bone construct of Mikos and the *in vitro* cartilage construct of Itay to yield a composition comprising cultured cartilage on one side and cultured bone on the opposite side because Jakob et al. teach that compositions so configured may be implanted into the articular portions of bones to effectively treat defects.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants allege that the proper analysis of the instant claims is “whether a functional joint can be generated *in vitro* and not whether the resulting product looks like the real thing” (Reply, page 10, paragraph 6) and “whether [the art] in anyway [sic] teach, suggest, motivate, or otherwise point to the likelihood of success of an attempt to engineer a functional biological joint *in vitro* (Reply, page 11, paragraph 1). Applicants further urge that the art does not teach “finding a way, *in vitro*, to integrally connect the cartilage side and the osseous side in order to engineer an orthopedically functional joint construct” (Reply, page 11, paragraph 5) and that prosecution has been hindered

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in some way by the examiner's insistence on treating the instant invention only as a composition (Reply, page 11, paragraph 6). Applicants allege that the composition comprises an "interlocking zone" that renders the invention patentable (Reply, page 11, paragraphs 2 and 3). Applicants allege that the term "consisting essentially of" should not be interpreted as "comprising" (Reply, page 12, paragraphs 3 and 4). Applicants allege both that the instant construct is "as close in structure and function to a natural joint as possible (Reply, page 10, paragraph 7 et seq.) and that it is "designed to approximate a natural joint as functionally and anatomically as possible in a laboratory setting" (Reply, page 13, paragraph 1), but that it is not identical to the natural construct of Jakob (Reply, page 12, paragraph 5). These arguments have been fully considered, but they are not persuasive.

The majority of applicants' arguments regard the manner in which the composition may be made, not the composition per se. In the restriction requirement mailed 9/28/04, applicants were given the opportunity to choose between prosecuting a composition and prosecuting a method of making the same (*id.*, page 2). On 10/28/04, applicants replied and elected the composition with traverse, and on 12/6/04, the traverse was found unpersuasive and the restriction requirement was made final (see Office action, page 3). Whether or not the art teaches a particular method for making a composition is not at issue in this case, in which the elected claims are drawn to a composition and only a composition. As discussed above, the burden in showing the nonobviousness of compositions described using product-by-process limitations shifts to applicants, and there is simply no evidence on the record that the composition **as**

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claimed would be different than that suggested by the prior art as set forth in the rejection. A proper interpretation of the claims reveals that they do not exclude any components (see below).

Regarding the “interlocking zone,” this limitation is discussed at page 5, line 31, et seq. of the specification, but the physical properties of this zone or area are not pointed out. Applicants have repeatedly urged that the presence of this zone is inventive (see, e.g., the instant reply at page 11, paragraph 4), but it is not clear what structure or function this zone necessarily possesses and which it may not possess.

As discussed above and previously, the basic and novel characteristics of a composition must be set forth in the specification or the claims, **not** in applicant's arguments as is currently alleged. There is no basis for applicants' statement that the instant composition does not contain osteoclasts (see instant reply at page 12, paragraph 4), because the method in the product-by-process limitation **comprise** 8 particular steps; there is no requirement that osteoclasts are never added.

Again, applicants' arguments about the distinction between the instant composition and that suggested by the prior art are contradictory and confusing. On one hand, applicants allege that the “inventive genius” is the similarity between the instant construct and a natural product (page 10, paragraph 7); on the other hand, applicants allege that the instant composition is distinct from a natural product (page 12, paragraph 8 et seq.). Resolution of this matter is necessary to determine the gist of applicants' arguments, and it has been heretofore impossible.

In summary, this rejection is based on the well known teachings of the prior art that bone and cartilage cells may be cultured *in vitro* on the same type of scaffold and that compositions comprising bone on one side and cartilage on the opposing side are useful for treating bone defects. Applicant has not provided arguments or evidence to support the nonobviousness of combining these teachings as set forth by the examiner, *e.g.* a showing of secondary considerations or a persuasive argument that the cited prior art is non-analogous. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Claim 37 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Mikos, Rosenthal et al., and Jakob et al. as applied to claims 36, 38, 41, 42, 44, 67, and 68 above, and further in view of Goldstein et al. (1999, U.S. Patent 5,962,427) and Vacanti et al. (1998, U.S. Patent 5,804,178).

The teachings of Itay, Mikos, Rosenthal et al., and Jakob et al. are relied upon as above. Furthermore, Itay teaches that the *in vitro* cartilage composition may include progenitor cells of mesenchymal origin, bone marrow stromal cells, or any undifferentiated mesenchymal cells (column 3, lines 35-46) and may include additional active agents including serum (column 3, lines 47-52).

Itay, Mikos, Rosenthal et al., and Jakob et al. do not teach or suggest including a growth factor that promotes angiogenesis or including endothelial cells or their progenitors in the composition.

Goldstein et al. teach that including DNA encoding vascular endothelial growth factor (VEGF) in an implanted biocompatible matrix promotes angiogenesis at the implant site by transfecting nearby cells (column 2, lines 21-36; column 14, lines 13-45; and column 24, lines 7-29). The matrix of Goldstein et al. may be any biodegradable matrix (column 11, line 19, through column 14, line 4), including PGA (column 12, line 35). Goldstein et al. also teach administering recombinant VEGF protein (column 2, line 42, through column 3, line 31).

Vacanti et al. teach implanting endothelial cells in a biodegradable matrix such as PGA (Abstract; column 3, lines 5-41; column 4, lines 52-57; column 5, lines 49-50).

A person of ordinary skill in the art would have had a reasonable expectation of success in including either pro-angiogenic growth factors (such as VEGF) or cells carrying cDNAs therefor or endothelial cells *per se* (which are required structural components of blood vessels) in the composition of Itay in view of Mikos, Rosenthal et al., and Jakob et al. because Itay suggests including additional cell types and additional active agents and because Goldstein et al. and Vacanti et al. teach that VEGF protein, VEGF cDNA, cells transfected with VEGF cDNA, and endothelial cells may be implanted using a biocompatible matrix equivalent to those employed by Itay and Mikos. The skilled artisan would have been motivated to include endothelial cells and/or pro-angiogenic growth factors for the expected benefit of increasing the degree of vessel formation around the implant after it has been placed into a recipient, thus improving the implant's ability to incorporate into the recipient's body.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include the pro-angiogenic factors of Goldstein et al. or the endothelial cells of Vacanti et al. in the composition of Itay taken in view of Mikos, Rosenthal et al., and Jakob et al. because Goldstein et al. and Vacanti et al. teach that these components improve angiogenesis upon implantation of such a composition, thus increasing the chance that the composition successfully engrafts in a patient.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that the examiner employed impermissible hindsight in rejecting claim 37 (Reply, page 13, paragraphs 5 and 6). Applicants allege that the tissue culture art is unpredictable and urge that if the invention were obvious, the claimed composition would have been made before (*ibid.*). Applicants allege that the prior art does not anticipate the invention (Reply, page 14, paragraph 2). These arguments have been fully considered, but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As set forth in the rejection, each aspect of the instant invention was known at

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the time of filing, and the art recognized the desirability of combining the elements of the prior art. Therefore, the examiner has employed only permissible hindsight, i.e. that required to determine what would have been obvious at the time of the invention, in making the rejection.

Regarding applicants' statement that the prior art does not anticipate the invention, it is noted for the record that this rejection is over 35 U.S.C. § 103, not § 102. Anticipation is not necessarily a factor in determining obviousness.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for **any** amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651